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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,509	08/20/2008	Fredika Robertson	22727/04421	2169

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EXAMINER

SAUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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06/24/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com
dcunin@calfee.com

Office Action Summary	Application No. 10/597,509	Applicant(s) ROBERTSON ET AL.	
	Examiner Christine J. Saoud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-15, 18-20 and 22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 2, 16, 21, 23 and 24 is/are allowed.
- 6) ☒ Claim(s) 3-7 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 24 March 2010 is acknowledged.

Claims 8-15, 18-20, and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 24 March 2010.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

At the time of the instant Office action, no IDS had been received into the instant application.

Specification

The disclosure is objected to because of the following informalities: the explanation of Figure 6 in the Brief Description of the drawings is lacking the Sequence

Art Unit: 1647

identifiers for the sequences which are present in the Figure. 37 CFR 1.821(d) requires the use of a Sequence identifier whenever reference to a sequence in the Sequence Listing is made. Alternatively, the Sequence identifiers could be added to the Figure but typically, it is easier to add the SEQ ID NO's to the specification. See also Figure 7, which requires the use of Sequence identifiers in either the Figure or the Brief Description of the Figure.

Appropriate correction is required.

Claim Objections

Claim 7 is objected to because of the following informalities: the claim appears to be missing the word "of" immediately preceding the term "vascular". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are an isolated polypeptide comprising an amino acid sequence of 7 amino acids, wherein the polypeptide stimulates a protein kinase B signaling pathway, or binds to vascular endothelial growth factor receptor 2. However, the instant specification lacks an adequate written description of polypeptides which comprise 7 amino acids (SEQ ID NO:16) and have the function required in the claims.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession a VEGF polypeptide of SEQ ID NO:1 which has the ability to stimulate a protein kinase B signaling pathway or which binds to vascular endothelial growth factor receptor 2. However, the instant specification fails to provide a written description where the only recited structure is the amino acid sequence of SEQ ID NO:16 and where the polypeptide has the recited functions of the claims.

The subject matter which is claimed is described above. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are also directed to polypeptides which comprise the amino acid sequence of SEQ ID NO:16 and which has the ability to stimulate a protein kinase B signaling pathway or which binds to vascular endothelial growth factor receptor 2. First, the claims do not recite sufficient structure to provide for the function recited in the claims. Next, there are other naturally occurring proteins

Art Unit: 1647

which contain this amino acid sequence which do not have the recited function in the claims. Therefore, there is a lack of guidance or teaching regarding structure and function because there is only a single example provided in the specification (full-length SEQ ID NO:1) and because guidance is not found in the prior art with regard to polypeptides comprising the amino acid sequence of SEQ ID NO:16 and the functions recited in the claims. The claims do not recite any particular structure for the claimed polypeptide which would provide for the recited activities of the claimed polypeptides.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claims except for the polypeptide of SEQ ID NO:1. The specification does not provide a complete structure of those polypeptides which comprise the amino acid sequence of SEQ ID NO:16 wherein the polypeptide has the ability to stimulate a protein kinase B signaling pathway or which binds to vascular endothelial growth factor receptor 2. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The specification fails to provide

Art Unit: 1647

a representative number of species for the claimed genus (polypeptides which comprise the amino acid sequence of SEQ ID NO:16). Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites a “method of inducing migration and/or organization and/or survival vascular endothelial cells”, however, it is not clear how the claimed protein could induce migration without also inducing survival since these properties appear to be mediated by the same receptor when activated with the protein of SEQ ID NO:1. Additionally, it is not clear what is intended by the term “organization”. Therefore, the metes and bounds of what is being claim is not clear.

Claim 17 recites “wherein the device or implant comprises a suture”, however, it is not clear how a device or implant comprises a suture based on the ordinary meaning of the term suture. As a medical application for the term, a suture is a stitch made with suture material. Therefore, it is not clear how an implant or device can comprise a suture and the metes and bounds of what is being claim is unclear.

Allowable Subject Matter

Claim 1-2, 16, 21 and 23-24 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647